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The Effects of Daily Ginger Tea Consumption in Reducing Period Discomfort

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The Effects of Daily Ginger Tea Consumption in Reducing Period Discomfort

Research Snapshot

Research Question: Does daily consumption of ginger tea reduce period discomfort?

Key Findings: In this qualitative interventional study that included 16 female participants, who were aged 18 years and above, daily consumption of ginger tea may be associated with reduced period discomfort.

Abstract

Background

Ginger has been known for its medicinal purposes which includes treating inflammation.[6] Researchers have observed the effects of ginger capsules to alleviate dysmenorrhea, but few studies have investigated the use of ginger tea.[6,7,9,10,11] The effects of ginger tea on adolescent females have been studied and researchers concluded that ginger reduces menstrual discomfort.[1,2]

Objective

The purpose of our study was to observe the effects of daily ginger tea consumption on menstrual discomfort in non-adolescent menstruating women.

Design

Our study was a quantitative, interventional study.

Participants/setting

Subjects were females aged 18 years and above. Participants were mostly students from Loma Linda University.

Intervention

At the end of the first menstrual cycle to the start of the second menstrual cycle, subjects did not take ginger tea, home remedies, and pain medications. Subjects filled out the SF-36 survey, Pittsburgh Sleep Quality Index, Cohen Perceived Stress survey, a visual analog pain scale and a symptoms checklist during menstruation. Starting at the end of the second menstrual cycle to the start of the third menstrual cycle, subjects drank ginger tea daily and filled out the same set of questionnaires and surveys.

Main Outcome measures

Period pain was measured using a visual analogue pain scale. The symptoms checklist consisted of 19 symptoms associated with menstruation.

Statistical analyses performed

Data were analyzed using the SPSS software. A Paired Sample T-test was used to compare the effects of ginger tea on pain and symptoms experienced before and after the ginger tea intervention.

Results

Results demonstrated a significant decrease in maximum and mean number of symptoms experienced by subjects before and after ginger the tea intervention ($p = .013, .013$, respectively). There was also a decrease in maximum and mean pain experienced by subjects before and after ginger the tea intervention ($p = .092, .093$, respectively).

Conclusions

Our study shows promising results that daily ginger tea consumption may help reduce menstrual pain and discomfort.

Introduction

Dysmenorrhea is the most common gynecological symptom reported by women.[1] It comes from a Greek root meaning difficult menstrual flow. [1] Dysmenorrhea can be divided into two broad categories - primary and secondary dysmenorrhea. Primary dysmenorrhea is defined as cramping pain experienced before or during menstruation with the absence of identifiable pelvic pathology. Secondary dysmenorrhea, is menstrual pain associated with underlying pelvic pathology such as endometriosis. [1] With primary dysmenorrhea, pain is due to myometrial activity resulting in uterine ischemia. Prostaglandin synthesis modulates and amplifies myometrial activity.[1] Primary dysmenorrhea symptoms are often associated with time lost from school, work, or other activities. [2] Prevalence rates of primary dysmenorrhea are as high as 90 percent with one third reporting moderate or severe symptoms. [3] Many factors come into play as to why these symptoms occur such as age, early menarche, heavy menstrual flow, and family history.[1] For this reason, we have decided to focus on primary dysmenorrhea in our research study since it affects many women.

Women do not seek medical treatment for primary dysmenorrhea symptoms most often. Instead, over-the-counter pain relievers such as acetaminophen or NSAIDs, oral contraceptives, exercise, heat patches, and herbal supplements are used, with research showing these treatment options to be effective in some women. [1,2,4-8] Unfortunately, symptom relief is occasionally accompanied with other undesirable side effects such as diarrhea, stomach pain, and nausea when medications are used.[4]

Alternative treatments, such as minerals, vitamins, and herbal supplements, have shown positive results. Hosseinlou found fish oil and vitamin B1 supplementation to significantly decrease pain intensity in women with dysmenorrhea.[8] In addition, boron, known for having anti-inflammatory effects, appears to be effective in reducing the severity and duration of menstrual pain when taken as a supplement according to Nikkhah.[5] Also,

a double-blind crossover study by Rahbar, found supplementation with omega-3 fatty acids reduced menstrual discomfort. [6]

Another alternative treatment involves the use of ginger. For many years, ginger has been used as an herbal supplement to treat painful diseases and has been known to have medicinal purposes.[4] The Food and Drug Administration (FDA) has labeled ginger as a safe herbal supplement for its known anti-inflammatory effect.[4] Researchers have observed the effect of capsulated ginger supplements on reducing the severity of dysmenorrhea.[4,7,9] A randomized study by Kashefi compared the effects of ginger and zinc sulfate on primary dysmenorrhea among high school students.[4] Results showed that both ginger and zinc sulfate supplementation have positive effects in reducing primary dysmenorrhea symptoms. Another study by Ozgoli, compared the effects of ginger supplementation, mefenamic acid, and ibuprofen.[7] Results showed ginger to be just as effective as mefenamic acid and ibuprofen in reducing pain. Thus, the use of ginger supplementation to reduce the severity of menstrual symptoms is an established research topic.

Very few studies have investigated the use of ginger tea as an intervention. Amutha and Kavuluru studied the effect of ginger tea on adolescent females. Both concluded ginger to have a positive effect in alleviating menstrual discomfort.[10,11] Therefore, the purpose of our graduate student research study is to observe the effects of daily ginger tea consumption in reducing menstrual discomfort in menstruating women.

Materials and Methods

For this quantitative, experimental study, approval from the Loma Linda University Institutional Review Board was obtained. Subjects consisted of 16 menstruating females aged 22-29 years. Recruitment of subjects took place soon after approval from IRB was obtained. Subjects were recruited through word of mouth, flyers posted around campus, and emails sent through LLU webmail. Each subject was part of both the control and intervention group.

Although subjects may not have personally benefited from this study, their participation may help practitioners provide scientific information that may aid women and healthcare professionals on improving treatment for period discomfort.

When obtaining subjects who would fit our target population, we set up both Inclusion and exclusion criteria. Inclusion criteria of subjects included being a female within the age range (18-50 years old), with regular menstrual cycles and experiencing period cramps, and agreed to refrain from taking any pain medications, herbal supplements, or use home remedies such as heating pads that are known to alleviate menstrual cramps during the study period. Also, subjects agreed to drink ginger tea daily. Exclusion criteria included those who took oral contraceptives, worked night shifts, were allergic to ginger, lactating, or women with female related uterine problems such as fibroids and polycystic ovarian syndrome who suffered from secondary dysmenorrhea.

The intervention for this study included Swanson 100% Certified Organic Ginger Root Tea, which was given to subjects. Each subject used one tea bag, which contains two grams ginger root per day during the tea intervention period. The tea bag was mixed with eight ounces of boiling water, steeped for three minutes, and allowed to cool to room temperature before drinking. This was performed every day for one month after the completion of their second menstruation cycle and during their third menstruation cycle.

Another instrument used was the SF-36 survey. Developed by Research and Development Corporation (RAND), this is a validated survey measuring the quality-of-life of individuals.[12] The measures rely upon patient self-reporting and is widely utilized by managed care organizations and by Medicare for routine monitoring and assessment of care outcomes in adult patients.[12] This survey consists of eight scaled scores which are the weighted sums of the questions in each section. The sections include vitality, physical functioning, bodily pain, physical role functioning, general health perception, emotional role

functioning, social role functioning, and mental health. Each scale is transformed into a 0-100 scale and the lower score indicates more disability while the higher, represents less disability. The participants completed the survey in about half an hour and was assessed over a one-month period. A number 1 indicated much better now than one year ago, up to a 4, which indicated much worse now than one year ago.

A third tool used was the Pittsburgh Sleep Quality Index (PSQI). This is a validated self-report questionnaire that assesses sleep quality over a one-month time interval.[13] The measure consists of 19 individual items, creating seven components that produce one global score, and takes 5–10 minutes to complete. The survey was developed by researchers in the University of Pittsburgh and it is intended to be a standardized sleep questionnaire for clinicians and researchers to use with ease. The PSQI has been used in many settings such as research and clinical activities and has been used in the diagnosis of sleep disorders.[13]

The fourth instrument used, was the Cohen Perceived Stress survey. The PSS was developed by Sheldon Cohen and his colleagues and was published in 1983.[14] The PSS has become one of the most widely used psychological instruments for measuring nonspecific perceived stress and is used in assessing stressfulness of situations, the effectiveness of stress-reducing interventions, and the extent to which there are associations between psychological stress and psychiatric and physical disorders. The survey took on average about 5-10 minutes to complete.

Furthermore, a visual analogue scale developed by student investigators, was used to assess pain. It is a form of Likert scale that gives the interviewee maximum freedom to estimate their pain intensity. The interviewee marked a vertical line along the 10-cm scale which they perceived corresponded best to their exact pain intensity every day during menstruation. A score of zero indicated no pain and a score of 10 indicated the most severe pain felt.

Finally, a compliance sheet developed by student investigators was used to estimate tea consumption compliance. Subjects were given a sheet with a table listing days on one column, another column to place a check mark if tea was consumed, and a third column to explain why they did not drink tea that day. Student investigators called or texted subjects weekly to check compliance and asked if they had any questions.

Statistical Analysis

Data obtained from the study was analyzed through SPSS software. A Paired Samples T-Test was used to compare the effect of ginger tea on pain and symptoms experienced before and after the ginger tea intervention.

Procedures

On the first day, student investigators discussed the introduction, purpose, procedures, and compliance with subjects. Subjects were then asked if they agreed to take ginger tea daily for a month. They were also asked if they had regular menstrual cycles and agreed to stop home remedies, stop taking pain medications or herbal supplements for a period of three menstruation cycles. Then, subjects signed the informed consent document.

At the start of their first menstrual cycle, subjects met with student investigators at a convenient location for the subjects and completed surveys and questionnaires. Subjects were given visual analog pain scales and symptom checklists that were then completed at the end of each day during their second menstruation cycle. Then, at the end of the first menstrual cycle to the start of the second menstrual cycle, subjects did not take ginger tea, avoided home remedies, and refrained from taking pain medications or supplements.

During the start of the second menstrual cycle to the end of the second menstrual cycle, subjects met with student investigators again at a mutually convenient location and completed surveys and questionnaires. Subjects rated menstrual symptoms using the visual

analog pain scales and symptom checklist during menstruation. Subjects were given daily logs, visual analog pain scales, symptom checklists, and supplies for the ginger tea.

Starting at the end of the second menstrual cycle to the start of the third menstrual cycle, subjects drank ginger tea daily, avoided home remedies, refrained from taking pain medications and supplements, and kept track of ginger tea intake by placing a check mark each day in the daily log checklist. At the start of the third menstruation cycle to the end of the third menstruation cycle, subjects drank ginger tea daily. Subjects rated menstrual symptoms using the visual analog pain scales and the symptom checklist at the end of each day during menstruation. Finally, once the third menstrual cycle ended, subjects met with student investigators at a location convenient for the subject and turned in daily logs, visual analog pain scales, and symptom checklists.

Results

There were 21 subjects enrolled and 16 completed the study. Four subjects ceased contact and one did not refrain from taking pain medication because her pain was very severe. There was a compliance rate of 87.5%. Since the study occurred during the winter season, subjects reported skipping days due to holidays and traveling.

The average age of the 16 subjects was 24.6 years (SD = 2.5). All subjects participated in weekly physical activity. Physical activity was ranked as either light, moderate, or intense physical activity. Light activity was defined as 1-2 days per week, moderated 3-5 days per week, and intense 5-7 days per week. Of the 16 subjects, 9 were in the light category, 5 were in the moderate, and 2 were in the intense category.

Figure 1 illustrates a decrease in both maximum and average pain experienced by subjects before and after daily ginger tea consumption over one month. The maximum pain before intervention was 5.82 and after ginger tea intervention, it decreased to 4.67. The average pain before intervention was 0.33 and after ginger tea intervention, average pain decreased to 0.17. Maximum and average pain showed no significant results ($p = .092, .093$ respectively).

Figure 2 illustrates a decrease in both maximum and average number of symptoms experienced by subjects before and after daily ginger tea consumption over one month. Before intervention, maximum number of symptoms experienced by subjects was 5.56 and post intervention, maximum symptoms decreased to 3.63. Average symptoms prior to intervention was 2.45 and post intervention, average symptoms decreased to 1.61. Both values showed a significant decrease ($p = .013, .013$, respectively).

Table 1 shows there was no changes between sleep, stress, and quality of life surveys when comparing baseline to ginger tea intervention.

Discussion

The purpose of our study was to observe the effects of daily ginger tea consumption in reducing menstrual discomfort in menstruating women. To the best of our knowledge, few research studies have been conducted to observe the effects of daily ginger tea consumption in reducing menstrual discomfort.[10,11] Similar to researchers who examined the effect of ginger supplements and ginger tea in reducing primary dysmenorrhea, our research has found a reduction in both menstrual pain and symptoms with the use of ginger tea.[7, 10, 11]

As our study showed, ginger's effect on reducing menstrual discomfort could be attributed to its anti-inflammatory properties. Specifically, gingerol-related compounds found in ginger, such as 10-gingerol and gingerdiones, can selectively inhibit the inducible form of cyclooxygenase 2 (COX-2) enzymes but not the constitutive form of cyclooxygenase 1 (COX-1) enzymes.[15] Both COX-1 and COX-2 are enzymes that produce prostaglandins, which are compounds that promote inflammation in the body. Cyclooxygenase 1 is expressed in normal tissues to maintain homeostatic functions, while COX-2 are often induced and expressed during inflammatory processes.[15] This suggests that ginger's anti-inflammatory properties seen in inhibiting COX-2 pathways may be the explanation to its ability in reducing menstrual pain, as showcased in the results of our study. The reduction in pain scores, as well as the reduction in numbers of symptoms before and after ginger tea intervention may very well be the result of the anti-inflammatory effects of gingerol-related compounds. Furthermore, a review on the gastroprotective effects of ginger also showed its effectiveness in treating gastric ailments such as belching and bloating.[17] Thus, suggesting that ginger tea may have contributed to the reduction in maximum and mean symptoms amongst participant after ginger tea intervention as seen on figure 2. Therefore, ginger tea may be a natural remedy women can use in place of or in conjunction with the other methods they currently use to help with menstrual discomfort.

There were several strengths in our study. A strength of our study was participants acted as their own control thus reducing potential confounders and variance due to individual differences among participants. In addition, most studies conducted on ginger tea and menstrual discomfort have only compared its effect on adolescent females.[10, 11] However, our study, was conducted on women ranging from 20-28 years old.[10,11] Therefore, this suggests that the ability of ginger's anti-inflammatory properties to alleviate period discomfort can be extended to females beyond the adolescent years.

Apart from the strengths of the study, there were also limitations associated with the study. These limitations included a small sample size and a narrow age range. Also, all women who participated in this study were college students who may experience school related stress throughout the study duration. Stress may contribute to menstrual pain which may have contributed to the lack of significance in reducing menstrual pain.[12] In addition, it has been established that prostaglandins, which is a COX-2 derived mediators, is activated by the brain in the presence of stress.[16] Further research may include a larger sample size with a wider age range, women of different occupational backgrounds, the appropriate dosage required for optimal effect, and how stress may contribute to menstrual discomfort.

Conclusion

In conclusion, our study shows promising results that daily consumption of ginger tea may help reduce menstrual pain and other symptoms that are associated with period discomfort. This could allow women to spend less time in pain and discomfort; therefore, increasing productivity of their daily living activities and improving their overall quality of life. Considering the negative side effects other treatments such as pain medications may provide, ginger tea gives women another natural treatment option to reduce discomfort.

References

1. Lefebvre G, Pinsonneault O, Antao V, et al. Primary dysmenorrhea consensus guideline. *Journal of obstetrics and gynaecology Canada : JOGC = Journal d'obstetrique et gynecologie du Canada : JOGC.* 2005;27(12):1117-1146.
2. Hillen TI, Grbavac SL, Johnston PJ, Straton JA, Keogh JM. Primary dysmenorrhea in young Western Australian women: prevalence, impact, and knowledge of treatment. *The Journal of adolescent health : official publication of the Society for Adolescent Medicine.* 1999;25(1):40-45.
3. Jamieson DJ, Steege JF. The prevalence of dysmenorrhea, dyspareunia, pelvic pain, and irritable bowel syndrome in primary care practices. *Obstetrics and gynecology.* 1996;87(1):55-58.
4. Kashefi F, Khajehei M, Tabatabaeichehr M, Alavinia M, Asili J. Comparison of the effect of ginger and zinc sulfate on primary dysmenorrhea: a placebo-controlled randomized trial. *Pain management nursing : official journal of the American Society of Pain Management Nurses.* 2014;15(4):826-833.
5. Nikkhah S, Dolatian M, Naghii MR, Zaeri F, Taheri SM. Effects of boron supplementation on the severity and duration of pain in primary dysmenorrhea. *Complementary therapies in clinical practice.* 2015;21(2):79-83.
6. Rahbar N, Asgharzadeh N, Ghorbani R. Effect of omega-3 fatty acids on intensity of primary dysmenorrhea. *International journal of gynaecology and obstetrics: the official organ of the International Federation of Gynaecology and Obstetrics.* 2012;117(1):45-47.
7. Ozgoli G, Goli M, Moattar F. Comparison of effects of ginger, mefenamic acid, and ibuprofen on pain in women with primary dysmenorrhea. *Journal of alternative and complementary medicine (New York, NY).* 2009;15(2):129-132.

8. Hosseinlou A, Alinejad V, Alinejad M, Aghakhani N. The effects of fish oil capsules and vitamin B1 tablets on duration and severity of dysmenorrhea in students of high school in Urmia-Iran. *Global journal of health science.* 2014;6(7 Spec No):124-129.
9. Jenabi E. The effect of ginger for relieving of primary dysmenorrhoea. *JPMA The Journal of the Pakistan Medical Association.* 2013;63(1):8-10.
10. Amutha V. *Effectiveness of ginger tea on dysmenorrhea among college students in Sree Mookambika College of Nursing*, Sree Mookambika College of Nursing, Kulasekharam; 2016.
11. Kavuluru VP. A study to assess the effectiveness of ginger preparation on dysmenorrhea among adolescent girls. *IJAR.* 2017;3(3):22-25.
12. Hays RD, Morales LS. The RAND-36 measure of health-related quality of life. *Annals of medicine.* 2001;33(5):350-357.
13. Buysse DJ, Reynolds CF, 3rd, Monk TH, Berman SR, Kupfer DJ. The Pittsburgh Sleep Quality Index: a new instrument for psychiatric practice and research. *Psychiatry research.* 1989;28(2):193-213.
14. Cohen S, Kamarck T, Mermelstein R. Perceived stress scale. *Measuring stress: A guide for health and social scientists.* 1994.
15. Van Breemen RB, Tao Y, Li W. Cyclooxygenase-2 inhibitors in ginger (Zingiber officinale). *Fitoterapia.* 2011;82(1):38-43.
16. Ju H, Jones M, Mishra G. The prevalence and risk factors of dysmenorrhea. *Epidemiologic reviews.* 2013;36(1):104-113.
17. Haniadka R, Saldanha E, Sunita V, Palatty PL, Fayad R, Baliga MS. A review of the gastroprotective effects of ginger (Zingiber officinale Roscoe). Food & function. 2013;4(6):845-855.

Appendix A

Informed Consent Document

LOMA LINDA UNIVERSITY
School of Allied Health Professions

INFORMED CONSENT

THE EFFECTS OF DAILY GINGER TEA CONSUMPTION IN REDUCING DISCOMFORT DURING MENSTRUATION

PRINCIPAL INVESTIGATOR: Kyndra Woosley, MS, RD, Assistant Professor, Department of Nutrition and Dietetics, School of Allied Health Professionals
Graduate Student Investigators: Sherllie Kartika and Kristy Valencia

WHY IS THIS STUDY BEING DONE?

The purpose of this graduate student research is to study the effects of daily drinking of ginger tea on period discomfort in females with regular menstrual cycles.

You are invited to be in this study because you are a 18-50 years old female with a regular menstruation cycle and experiencing period discomfort, agree to drink ginger tea daily for one month, and agree to avoid taking any pain medications, herbal supplements, or use home remedies such as heating pads that are known to lessen the intensity of menstrual discomfort for the entire study period.

You are excluded from the study if you are taking oral contraceptives, allergic to ginger, work night shifts, lactating, or have female-related uterine problems such as fibroids and polycystic ovarian syndrome and suffer from other forms of menstrual pain apart from period cramps.

You will be required to avoid taking anything to alleviate your period discomfort for the first month. The second month, you will be required to avoid taking anything to help your period discomfort and drink ginger tea daily.

Approximately 50 subjects will participate in this study at the comfort of your own home apart from four meeting times, which will take place in a convenient location at Loma Linda University over the course of three months.

HOW WILL I BE INVOLVED?

Participation in this study involves the following:

Visit 1

- You will sign informed consent.
- We will go over the introduction, purpose, procedures and compliance with you

- You will be given a sample of ginger tea used for the study and will be asked if you think you can drink this daily for a month.

Visit 2- During your first menstruation cycle

- You will complete sleep, stress, and quality of life surveys and questionnaires.
- You will be given visual analog pain scales and symptom checklists.

Visit 3- On the last day of your second menstruation cycle

- You will complete sleep, stress, and quality of life surveys and questionnaires.
- You will be given daily logs, visual analog pain scales, and symptom checklists (to be completed at the end of the day).
- You will be given supplies and instructions for tea.

Visit 4- On the last day of your third menstruation cycle

- You will report back to us to turn in daily logs, visual analog pain scales, and symptom checklists.
- You will complete sleep, stress, and quality of life surveys and questionnaires.
- At the completion of visit 4, you will be asked to participate in a 1-2 minutes video recording to share your experience. This is not required to participate in the study and is voluntary. You may say "no" to be videotaped and still be in the study. The video will be used for an end of the year student presentation.

WHAT ARE THE REASONABLY FORESEEABLE RISKS OR DISCOMFORTS I MIGHT HAVE?

This study may involve a possible breach of confidentiality and possible menstruation discomfort usually felt during your monthly menstrual cycle.

To minimize the risk of breach of confidentiality, we will store all your data in a locked cabinet, in a locked office. If menstrual discomfort is too severe, you may drop out of the study.

All records and research materials that identify you will be held confidential. Any published document resulting from this study will not disclose your identity without your permission. Information identifying you will only be available to the study personnel. All videos will be stored indefinitely with the Department of Nutrition and Dietetics, Loma Linda University.

WILL THERE BE ANY BENEFIT TO OTHERS OR ME?

Although you may not personally benefit from this study, your participation may help practitioners provide scientific information that may help women and the healthcare setting in terms of managing period discomfort with a more natural remedy.

WHAT ARE MY RIGHTS AS A SUBJECT?

Your participation in this study is entirely voluntary. You may refuse to participate or withdraw once the study has started. You do not give up any legal rights by participating in this study.

WHAT COSTS ARE INVOLVED?

There is no cost to you for participating in this study. The ginger tea and mason jar will be provided to you at no cost. At the end of the study, you are allowed to keep the mason jar at no cost to you.

WILL I BE PAID TO PARTICIPATE IN THIS STUDY?

You will be given a $10 gift card at the completion of the entire study period.

WHO DO I CALL IF I AM INJURED AS A RESULT OF BEING IN THIS STUDY?

If you feel you have been injured by taking part in this study, consult a physician or call 911 if the situation is a medical emergency. No funds have been set aside or any plans made to compensate you for time lost for work, disability, pain or other discomforts resulting from your participation in this research.

WHO DO I CALL IF I HAVE QUESTIONS?

Call 909-558-4647 or e-mail patientrelations@llu.edu for information and assistance with complaints or concerns about your rights in this study.

SUBJECT'S STATEMENT OF CONSENT

- I have read the contents of the consent form and have listened to the verbal explanation given by the investigator.
- My questions concerning this study have been answered to my satisfaction.
- Signing this consent document does not waive any rights nor does it release the investigators, institution or sponsors from their responsibilities.
- I may call Kyndra Woosley at (909) 558-1000 ext: 47242 if I have additional questions or concerns.
- I hereby give voluntary consent to participate in this study.

Signature of Subject

Printed Name of Subject

Date

INVESTIGATOR'S STATEMENT

I have reviewed the contents of this consent form with the person signing above. I have explained potential risks and benefits of the study.

Signature of Investigator

Printed Name of Investigator

Date

Appendix B

HIPAA

INSTITUTIONAL REVIEW BOARD
Authorization for Use of Protected Health Information (PHI)

Per 45 CFR §164.508(b)
RESEARCH PROTECTION PROGRAMS
LOMA LINDA UNIVERSITY | Office of the Vice President of Research Affairs
24887 Taylor Street, Suite 202 Loma Linda, CA 92350
(909) 558-4531 (voice) / (909) 558-0131 (fax)/e-mail: irb@llu.edu

TITLE OF STUDY:	THE EFFECTS OF DAILY GINGER TEA CONSUMPTION IN REDUCING DISCOMFORT DURING MENSTRUATION
PRINCIPAL INVESTIGATOR:	Kyndra Woosley, MS, RD, Assistant Professor, Department of Nutrition and Dietetics, School of Allied Health Professionals
Others who will use, collect, or share PHI:	All authorized personnel

The study named above may be performed only by using personal information relating to your health. National and international data protection regulations give you the right to control the use of your medical information. Therefore, by signing this form, you specifically authorize your medical information to be used or shared as described below.

The following personal information, considered "Protected Health Information" (PHI) is needed to conduct this study and may include, but is not limited to: name, address, telephone number, date of birth, and past and current medical history on your menstruation.

The individual(s) listed above will use or share this PHI in the course of this study with the Institutional Review Board (IRB) and the Office of Research Affairs of Loma Linda University.

The main reason for sharing this information is to be able to conduct the study as described earlier in the consent form. In addition, it is shared to ensure that the study meets legal, institutional, and accreditation standards. Information may also be shared to report adverse events or situations that may help prevent placing other individuals at risk.

All reasonable efforts will be used to protect the confidentiality of your PHI, which may be shared with others to support this study, to carry out their responsibilities, to conduct public health reporting and to comply with the law as applicable. Those who receive the PHI may share with others if they are required by law, and they may share it with others who may not be required to follow national and international "protected health information" (PHI) regulations such as the federal privacy rule.

Subject to any legal limitations, you have the right to access any protected health information created during this study. You may request this information from the Principal Investigator named above but it will only become available after the study analyses are complete.

Loma Linda University
Adventist Health Science Center
Institutional Review Board
Approved 10/3/17 Void after, 10/2/2018
5170502 Chair

IRB 6/20/2014

- This authorization does not expire, and will continue indefinitely unless you notify the researchers that you wish to revoke it.

You may change your mind about this authorization at any time. If this happens, you must withdraw your permission in writing. Beginning on the date you withdraw your permission, no new personal health information will be used for this study. However, study personnel may continue to use the health information that was provided before you withdrew your permission. If you sign this form and enter the study, but later change your mind and withdraw your permission, you will be removed from the study at that time. To withdraw your permission, please contact the Principal Investigator or study personnel at (909) 558-1000 ext: 47242

You may refuse to sign this authorization. Refusing to sign will not affect the present or future care you receive at this institution and will not cause any penalty or loss of benefits to which you are entitled. However, if you do not sign this authorization form, you will not be able to take part in the study for which you are being considered. You will receive a copy of this signed and dated authorization prior to your participation in this study.

I agree that my personal health information may be used for the study purposes described in this form.

Signature of Patient *or* Patient's Legal Representative	Date
Printed Name of Legal Representative (if any)	Representative's Authority to Act for Patient
Signature of Investigator Obtaining Authorization	Date

Loma Linda University
Adventist Health Science Center
Institutional Review Board
Approved 10/3/17 Void after 10/2/2018
#5170302 Chair Irene Loney

Appendix C

Flyer

Experiencing Period Cramps, Ladies?

VOLUNTEERS NEEDED!

The Effects of Daily Ginger Tea Consumption in Reducing discomfort during menstruation

Allied Health Nutrition & Dietetic Graduate Students Research Study

If you meet these requirements, we want you!

Who

- **Female 18-50 y.o. with regular menstruation cycle and experiencing period cramps**
- **Agrees to avoid pain medications or herbal supplements or home remedies such as heating pads that are known to relieve menstrual cramps for the entire study period**
- **Agrees to take ginger tea daily after sampling the ginger tea**
- **Without any female-related uterine problems, such as fibroids and polycystic ovarian syndrome**
- **Not lactating**
- **Not working night shifts**
- **Not taking any oral contraceptives**
- **Not allergic to ginger**

Loma Linda University
Adventist Health Sciences Center
Institutional Review Board
Approved 10/3/2017
5170302 Chair

What

- **The purpose of our graduate student research study is to observe the effect of drinking ginger tea daily on reducing period cramps**
- **You will be asked to avoid taking anything for your period cramps for a month and to take only ginger tea once daily for the second month of the study period**
- **The study will take approximately 3 months**

If interested please contact graduate student Sherllie Kartika, at skartika@llu.edu or at +1 (714) 576-9708

LOMA LINDA UNIVERSITY

Principal investigator is Kyndra Woosley, MS, RD, Assistant Professor
Loma Linda University, School of Allied Health

Appendix D

SF- 36

RAND HEALTH

36-Item Short Form Survey Instrument (SF-36)

RAND 36-Item Health Survey 1.0 Questionnaire Items

Choose one option for each questionnaire item.

1. In general, would you say your health is:

- ◯ 1 - Excellent
- ◯ 2 - Very good
- ◯ 3 - Good
- ◯ 4 - Fair
- ◯ 5 - Poor

2. **Compared to one year ago**, how would you rate your health in general **now**?

- ◯ 1 - Much better now than one year ago
- ◯ 2 - Somewhat better now than one year ago
- ◯ 3 - About the same
- ◯ 4 - Somewhat worse now than one year ago
- ◯ 5 - Much worse now than one year ago

The following items are about activities you might do during a typical day. Does **your health now limit you** in these activities? If so, how much?

	Yes, limited a lot	Yes, limited a little	No, not limited at all
3. **Vigorous activities**, such as running, lifting heavy objects, participating in strenuous sports	◯ 1	◯ 2	◯ 3
4. **Moderate activities**, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	◯ 1	◯ 2	◯ 3
5. Lifting or carrying groceries	◯ 1	◯ 2	◯ 3
6. Climbing **several** flights of stairs	◯ 1	◯ 2	◯ 3
7. Climbing **one** flight of stairs	◯ 1	◯ 2	◯ 3
8. Bending, kneeling, or stooping	◯ 1	◯ 2	◯ 3
9. Walking **more than a mile**	◯ 1	◯ 2	◯ 3
10. Walking **several blocks**	◯ 1	◯ 2	◯ 3
11. Walking **one block**	◯ 1	◯ 2	◯ 3
12. Bathing or dressing yourself	◯ 1	◯ 2	◯ 3

During the **past 4 weeks**, have you had any of the following problems with your work or other regular daily activities **as a result of your physical health**?

	Yes	No
13. Cut down the **amount of time** you spent on work or other activities	◯ 1	◯ 2
14. **Accomplished less** than you would like	◯ 1	◯ 2
15. Were limited in the **kind** of work or other activities	◯ 1	◯ 2
16. Had **difficulty** performing the work or other activities (for example, it took extra effort)	◯ 1	◯ 2

During the **past 4 weeks**, have you had any of the following problems with your work or other regular daily activities **as a result of any emotional problems** (such as feeling depressed or anxious)?

	Yes	No
17. Cut down the **amount of time** you spent on work or other activities	◯ 1	◯ 2
18. **Accomplished less** than you would like	◯ 1	◯ 2
19. Didn't do work or other activities as **carefully** as usual	◯ 1	◯ 2

20. During the **past 4 weeks**, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?

◯ 1 - Not at all

◯ 2 - Slightly

◯ 3 - Moderately

◯ 4 - Quite a bit

◯ 5 - Extremely

21. How much **bodily** pain have you had during the **past 4 weeks**?

◯ 1 - None

◯ 2 - Very mild

◯ 3 - Mild

◯ 4 - Moderate

◯ 5 - Severe

◯ 6 - Very severe

22. During the **past 4 weeks**, how much did **pain** interfere with your normal work (including both work outside the home and housework)?

- ◯ 1 - Not at all
- ◯ 2 - A little bit
- ◯ 3 - Moderately
- ◯ 4 - Quite a bit
- ◯ 5 - Extremely

These questions are about how you feel and how things have been with you **during the past 4 weeks**. For each question, please give the one answer that comes closest to the way you have been feeling.

How much of the time during the **past 4 weeks**...

	All of the time	Most of the time	A good bit of the time	Some of the time	A little of the time	None of the time
23. Did you feel full of pep?	◯ 1	◯ 2	◯ 3	◯ 4	◯ 5	◯ 6
24. Have you been a very nervous person?	◯ 1	◯ 2	◯ 3	◯ 4	◯ 5	◯ 6
25. Have you felt so down in the dumps that nothing could cheer you up?	◯ 1	◯ 2	◯ 3	◯ 4	◯ 5	◯ 6
26. Have you felt calm and peaceful?	◯ 1	◯ 2	◯ 3	◯ 4	◯ 5	◯ 6
27. Did you have a lot of energy?	◯ 1	◯ 2	◯ 3	◯ 4	◯ 5	◯ 6
28. Have you felt downhearted and blue?	◯ 1	◯ 2	◯ 3	◯ 4	◯ 5	◯ 6
29. Did you feel worn out?	◯ 1	◯ 2	◯ 3	◯ 4	◯ 5	◯ 6
30. Have you been a happy person?	◯ 1	◯ 2	◯ 3	◯ 4	◯ 5	◯ 6
31. Did you feel tired?	◯ 1	◯ 2	◯ 3	◯ 4	◯ 5	◯ 6

32. During the **past 4 weeks**, how much of the time has **your physical health or emotional problems** interfered with your social activities (like visiting with friends, relatives, etc.)?

- ◯ 1 - All of the time
- ◯ 2 - Most of the time
- ◯ 3 - Some of the time
- ◯ 4 - A little of the time
- ◯ 5 - None of the time

How TRUE or FALSE is **each** of the following statements for you.

	Definitely true	Mostly true	Don't know	Mostly false	Definitely false
33. I seem to get sick a little easier than other people	◯ 1	◯ 2	◯ 3	◯ 4	◯ 5
34. I am as healthy as anybody I know	◯ 1	◯ 2	◯ 3	◯ 4	◯ 5
35. I expect my health to get worse	◯ 1	◯ 2	◯ 3	◯ 4	◯ 5
36. My health is excellent	◯ 1	◯ 2	◯ 3	◯ 4	◯ 5

Appendix E

PSQI

PITTSBURGH SLEEP QUALITY INDEX (PSQI)

INSTRUCTIONS: The following questions relate to your usual sleep habits during the past month only. Your answers should indicate the most accurate reply for the majority of days and nights in the past month. Please answer all questions.

1. During the past month, when have you usually gone to bed at night?

   USUAL BED TIME _____

2. During the past month, how long (in minutes) has it usually take you to fall asleep each night?

   NUMBER OF MINUTES _____

3. During the past month, when have you usually gotten up in the morning?

   USUAL GETTING UP TIME _____

4. During the past month, how many hours of actual sleep did you get at night? (This may be different than the number of hours you spend in bed.)

   HOURS OF SLEEP PER NIGHT _____

INSTRUCTIONS: For each of the remaining questions, check the one best response. Please answer all questions.

5. During the past month, how often have you had trouble sleeping because you...

	Not during the past month	Less than once a week	Once or twice a week	Three or more times a week
(a) ...cannot get to sleep within 30 minutes	☐	☐	☐	☐
(b) ...wake up in the middle of the night or early morning	☐	☐	☐	☐
(c) ...have to get up to use the bathroom	☐	☐	☐	☐
(d ...cannot breathe comfortably	☐	☐	☐	☐
(e) ...cough or snore loudly	☐	☐	☐	☐
(f) ...feel too cold	☐	☐	☐	☐
(g) ...feel too hot	☐	☐	☐	☐
(h) ...had bad dreams	☐	☐	☐	☐
(i) ...have pain	☐	☐	☐	☐
(j) Other reason(s), please describe _____ _____				
How often during the past month have you had trouble sleeping because of this?	☐	☐	☐	☐

	Very good	Fairly good	Fairly bad	very bad
6. During the past month, how would you rate your sleep quality overall?	☐	☐	☐	☐

	Not during the past month	Less than once a week	Once or twice a week	Three or more times a week
7. During the past month, how often have you taken medicine (prescribed or "over the counter") to help you sleep?	☐	☐	☐	☐
8. During the past month, how often have you had trouble staying awake while driving, eating meals, or engaging in social activity?	☐	☐	☐	☐

	No problem at all	Only a very slight problem	Somewhat of a problem	A very big problem
9. During the past month, how much of a problem has it been for you to keep up enough enthusiasm to get things done?	☐	☐	☐	☐

	No bed partner or roommate	Partner/ roommate in other room	Partner in same room, but not same bed	Partner in same bed
10. During the past month, how much of a problem has it been for you to keep up enough enthusiasm to get things done?	☐	☐	☐	☐

If you have a roommate or bed partner, ask him/her how often in the past month you have had...

	Not during the past month	Less than once a week	Once or twice a week	Three or more times a week
(a) ...loud snoring	☐	☐	☐	☐
(b) ...long pauses between breaths while asleep	☐	☐	☐	☐
(c) ...legs twitching or jerking while you sleep	☐	☐	☐	☐
(d) ...episodes of disorientation or confusion during sleep	☐	☐	☐	☐
(e) Other restlessness while you sleep; please describe	☐	☐	☐	☐

SCORING INSTRUCTIONS FOR THE PITTSBURGH SLEEP QUALITY INDEX:

The Pittsburgh Sleep Quality Index (PSQI) contains 19 self-rated questions and 5 questions rated by the bed partner or roommate (if one is available). Only self-rated questions are included in the scoring. The 19 self-rated items are combined to form seven "component" scores, each of which has a range of 0-3 points. In all cases, a score of "0" indicates no difficulty, while a score of "3" indicates severe difficulty. The seven component scores are then added to yield one "global" score, with a range of 0-21 points, "0" indicating no difficulty and "21 " indicating severe difficulties in all areas.

Scoring proceeds as follows:

Component 1: Subjective sleep quality

Examine question #6, and assign scores as follows:

Response	Component 1 score
"Very good"	0
"Fairly good"	1
"Fairly bad"	2
"Very bad"	3

Component 1 score: _____

Component 2: Sleep latency

1. Examine question #2, and assign scores as follows:

Respo\nse	Score
≤15 minutes	0
16-30 minutes	1
31-60 minutes	2
> 60 minutes	3
Question #2 score:	_____

2. Examine question #5a, and assign scores as follows:

Response	Score
Not during the past month	0
Less than once a week	1
Once or twice a week	2
Three or more times a week	3
Question #5a score:	_____

3. Add #2 score and #5a score

Sum of #2 and #5a: _____

4. Assign component 2 score as follows:

Sum of #2 and #5a	Component 2 score
0	0
1-2	1
3-4	2
5-6	3

Component 2 score: _____

Component 3: Sleep duration

Examine question #4, and assign scores as follows:

Response	Component 3 score
> 7 hours	0
6-7 hours	1
5-6 hours	2
< 5 hours	3

Component 3 score:_____

Component 4: Habitual sleep efficiency

1. Write the number of hours slept (question #4) here:_____
2. Calculate the number of hours spent in bed:

   Getting up time (question #3):_____

   Bedtime (question #1):_____

   _____

   *Number of hours spent in bed:*_____

3. Calculate habitual sleep efficiency as follows:

   (Number of hours slept/Number of hours spent in bed) X 100 = Habitual sleep efficiency (%)

   (_____/_____) X 100 = %

4. Assign component 4 score as follows:

Habitual sleep efficiency %	Component 4 score
> 85%	0
75-84%	1
65-74%	2
< 65%	3

Component 4 score:_____

Component 5: Step disturbances

1. Examine questions #5b-5j, and assign scores for each question as follows:

Response	Score
Not during the past month	0
Less than once a week	1
Once or twice a week	2
Three or more times a week	3

5b score: _____

5c score: _____

5d score: _____

5e score: _____

5f score: _____

5g score: _____

5h score: _____

5i score: _____

5j score: _____

2. Add the scores for questions #5b-5j:

Sum of #5b-5j: _____

3. Assign component 5 score as follows:

Sum of #5b-5j	Component 5 score
0	0
1-9	1
10-18-4	2
19-27	3

Component 5 score: _____

Component 6: Use of sleeping medication

Examine question #7 and assign scores as follows:

Response	Component 6 score
Not during the past month	0
Less than once a week	1
Once or twice a week	2
Three or more times a week	3

Component 6 score: _____

Component 7: Daytime dysfunction

1. Examine question #8, and assign scores as follows:

Response	Score
Never	0
Once or twice	1
Once or twice each week	2
Three or more times each week	3

Question#8 score: _____

2. Examine question #9, and assign scores as follows:

Response	Score
No problem at all	0
Only a very slight problem	1
Somewhat of a problem	2
A very big problem	3

Question #9 score: _____

3. Add the scores for question #8 and #9:

Sum of #8 and #9: _____

4. Assign component 7 score as follows:

Sum of #8 and #9	Component 7 score
0	0
1-2	1
3-4	2
5-6	3

Component 7 score: _____

Global PSQI Score

Add the seven component scores together:

Global PSQI Score: _____

Appendix F

Cohen Perceived Stress Scale

PERCEIVED STRESS SCALE

The questions in this scale ask you about your feelings and thoughts during the last month. **In each case, you will be asked to indicate by circling *how often* you felt or thought a certain way.**

Name _____ Date _____

Age _____ Gender (*Circle*): **M F** Other _____

	0 = Never	**1 = Almost Never**	**2 = Sometimes**	**3 = Fairly Often**	**4 = Very Often**
1. In the last month, how often have you been upset because of something that happened unexpectedly?	0	1	2	3	4
2. In the last month, how often have you felt that you were unable to control the important things in your life?	0	1	2	3	4
3. In the last month, how often have you felt nervous and "stressed"?	0	1	2	3	4
4. In the last month, how often have you felt confident about your ability to handle your personal problems?	0	1	2	3	4
5. In the last month, how often have you felt that things were going your way?	0	1	2	3	4
6. In the last month, how often have you found that you could not cope with all the things that you had to do?	0	1	2	3	4
7. In the last month, how often have you been able to control irritations in your life?	0	1	2	3	4
8. In the last month, how often have you felt that you were on top of things?	0	1	2	3	4
9. In the last month, how often have you been angered because of things that were outside of your control?	0	1	2	3	4
10. In the last month, how often have you felt difficulties were piling up so high that you could not overcome them?	0	1	2	3	4

References

The PSS Scale is reprinted with permission of the American Sociological Association, from Cohen, S., Kamarck, T., and Mermelstein, R. (1983). A global measure of perceived stress. *Journal of Health and Social Behavior, 24,* 386-396.

Cohen, S. and Williamson, G. Perceived Stress in a Probability Sample of the United States. Spacapan, S. and Oskamp, S. (Eds.) *The Social Psychology of Health.* Newbury Park, CA: Sage, 1988.